K071321

BIO-DETEK INCORPORATED

SEP 12 2007

510(k) Summary:

Submitter's Name and Address:

Bio-Detek Incorporated

A Division of ZOLL Medical Corporation

525 Narragansett Park Drive

Pawtucket, RI 02861-4323
(401) 729-1400

Contact Person:

Robert Morse

(401) 729-1400 ext. 224

Date Summary Prepared:

July 31, 2007

Device:

PocketCPR™

Classification: Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Description:

PocketCPR™ is a device that uses voice prompts and visual indicators to assist rescuers in the performance of cardiopulmonary resuscitation (CPR). PocketCPR is designed to be used by a rescuer to perform CPR. PocketCPR provides rescuers with real-time feedback during the administration of CPR.

PocketCPR has two operating modes: Normal and Silent Operating Mode which allows the rescuer to perform CPR in any type of environmental condition. In Normal Operating Mode, PocketCPR operates with all sounds, including voice prompts and metronome beeping. In Silent Operating Mode, PocketCPR operates with visual flashing metronome and chest compression lights "only".

The PocketCPR directly measures acceleration through the use of an integrated accelerometer and instantaneously derives displacement. If the user is not compressing the chest at least 1.5 inches (38mm), the PocketCPR will instruct them to increase compression depth. The rate of compression is prompted by the use of a metronome signal, encouraging the rescuer to keep pace with the PocketCPR audible tone. After 30 compressions or about 18 seconds of chest compressions, PocketCPR will instruct the rescuer to give breaths.

Indications for Use:

To assist users in the performance of effective CPR on a victim 8 years or older.

Substantial Equivalence:

PocketCPR is substantially equivalent to CPR EZY and uses the technology substantially equivalent to CPR feedback in the ZOLL AEDPLUS® and ZOLL AEDPRO®. The features and functions of PocketCPR are based on the same technology as that found in the ZOLL AEDPLUS® and ZOLL AEDPRO®.

Performance Testing:

Extensive performance testing ensures that the PocketCPR meets all of its functional requirements and performance specifications.

Conclusion

Testing of the PocketCPR demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

Bio-Detek Incorporated
c/o Mr. Robert Morse
QA/QC Manager
525 Narragansett Park Drive
Pawtucket, Rhode Island 02861

Re: K071321
Pocket CPR™
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: Class III (three)
Product Code: LIX
Dated: August 8, 2007
Received: August 24, 2007

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K071321

Device Name: PocketCPR™

PocketCPR Function:

To assist users in the performance of effective CPR on a victim 8 years or older.

Rev 6

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]

[illegible] Control Number K071321